Appendix H



THE UNIVERD STAVES OF ANDER OF

TO ALL TO WHOM THESE; PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

December 13, 2023

THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE RECORDS OF THIS OFFICE OF THE FILE WRAPPER AND CONTENTS OF:

APPLICATION NUMBER: 12/944,591 FILING DATE: November 11, 2010 PATENT NUMBER: 8926490 ISSUE DATE: January 06, 2015



Certified by

Kathi

Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

REMARKS

The following remarks are in response to the Examiner's Office Action mailed on September 23, 2013. Claims 12, 15-19 and 21 are amended. Claim 22 is new. Previously withdrawn claims 1-11 are amended in kind with the amendments to elected claims 12-22 herein, in order to support potential rejoinder, as appropriate. Support for claim amendments and new claims can be found in the application as filed. See, *e.g.*, paragraphs paras [0152], [0164], [277], [0295], [0357], or [0560], at least. Reconsideration is respectfully requested in light of the following remarks.

Claim Rejections - 35 U.S.C. § 112 (Pre-AIA) Second Paragraph

Claims 15-19 and 21 were rejected under 35 U.S.C. § 112 (pre-AIA) second paragraph as being indefinite.

Applicants have amended Claims 15-17, as suggested by the Examiner, to depend from Claim 14, which provides antecedent basis for the limitations "the movement" and/or "said movement." Withdrawal of the rejection of Claims 15-17 under 35 U.S.C. § 112 (pre-AIA) second paragraph is appropriate and respectfully requested.

Applicants have amended Claims 18 and 19 for clarification to indicate the "intrinsic" frequency. Withdrawal of the rejection of Claims 18-19 under 35 U.S.C. § 112 (pre-AIA) second paragraph is appropriate and respectfully requested.

Applicants have amended Claim 21, to specify "said subject". Withdrawal of Claim 21 under 35 U.S.C. § 112 (pre-AIA) second paragraph is appropriate and respectfully requested.

Claim Rejections – 35 U.S.C. § 101

Claim 21 was rejected under 35 U.S.C. § 101 (pre-AIA and post-AIA) and section 33(a) of the AIA as being directed to or encompassing a human organism. Applicants thank the Examiner for the suggestion to amend the claim to recite "wherein the first electrode is adapted to be located on the subject" and "wherein the second electrode is adapted to be

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located on the subject". Withdrawal of the rejection of Claim 21 under 35 U.S.C. § 101 (pre-AIA and post-AIA) and section 33(a) of the AIA is appropriate and respectfully requested.

Claim Rejections – 35 U.S.C. § 103

Claims 12-21 are rejected under pre-AIA 35 U.S.C. § 103(a) as being obvious over US 6,001,055 (Souder) and in view of US 6,488,617 (Katz). Applicants traverse, for at least the reasons stated below.

To establish a *prima facie* case of obviousness, the cited art itself or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention are to have taught or suggested the claim elements. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007); *See also* MPEP § 2143.03. Thus, the Examiner must make "a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995). As such, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

The Office Action indicates that Souder fails to disclose or suggest multiple elements of Claim 12. Specifically, the Office Action states "Souder does not explicitly disclose that the device is capable of influencing an intrinsic frequency of a brain of the subject within a specified EEG band, a Q-factor [o]f an intrinsic frequency of the brain of the subject within a specified EEG band, a coherence of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band, and an EEG phase between two sites in the brain of the subject of a specified EEG frequency." Rather, the Office Action cites Katz for these elements. On the contrary, Katz fails to disclose or suggest any of these elements as filed, or as amended (for clarification).

The device of Katz describes <u>a feedback system</u>, which <u>in real time</u>, tries to move a subject <u>from a current brain state into a desired brain state</u> via magnetic stimulation. Brain states targeted in Katz are categorized based on the level of alertness of the subject. (Col. 1, line 14 to 34). These states include sleep states associated with brain wave frequencies in the delta and theta ranges of 1.5 to 3.5 Hz and 3.5 to 7 Hz, respectively, a relaxed state associated with brain wave frequencies in the alpha range of 7.5 to 12.5 Hz, and an excited

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state associated with brain wave frequencies in the beta range of 12.5 to 20 Hz (*Id., See also*, Col. 6, lines 16-35). Thus, each state of Katz is within a different EEG band, and Katz tries to move the subject from one state (in one band) to another state (in another band). At least the following distinctions can be made from the present claims.

Katz targets a desired brain <u>state</u>, which encompasses <u>a range</u> of frequencies in multiple bands. Claim 12 of the present invention requires moving an intrinsic frequency, not a state encompassing a range of frequencies. Further, movement of the intrinsic frequency of Claim 12 is within a <u>single</u> specified EEG band, and thus movement of the intrinsic frequency is within that single specified EEG band. In contrast, Katz' methods and devices move the subject's brain waves from one band to another, by teaching moving the subject from one brain state to a desired brain state. Brain states in Katz correlate to separate EEG bands in Katz (e.g. from relaxed in the alpha band to sleep in the delta or theta band).

Further, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject wherein the magnetic field moves a Q-factor of an intrinsic frequency of a brain of the subject within a specified EEG band as required in Claim 12.² As provided in the present application Figure 12, at least, and descriptions thereof, Q-factor is a measure of distribution around the intrinsic frequency within a single EEG band. Katz has no measurement or recognition of any such distribution around an intrinsic frequency, as it seeks to move brain states, without regard for any intrinsic frequency in a particular EEG band.

Likewise, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject wherein the magnetic field moves a subject's coherence value required in Claim 12.³ Katz expresses a goal of achieving **symmetry in magnitude** of the EEG readings starting with asynchronous magnetic fields (0.5Hz, 5Hz) (see Col. 8, line 39-60, at least). Thus, any **secondary** preference toward coherent waves appears to also use **asynchronous magnetic fields**. (See,

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¹ as a possible alternative to moving the Q-factor, coherence, or phase

² as a possible alternative to moving the intrinsic frequency, coherence, or phase

³ as a possible alternative to moving the intrinsic frequency, Q-factor, or phase

Column 8 line 39-60, at least). In contrast, Claim 12 requires⁴ moving a coherence value of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to a head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value.

Furthermore, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject wherein the magnetic field moves an EEG phase between two sites in the brain of the subject of a specified EEG frequency.

Finally, neither Katz nor Souder disclose or suggest comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject wherein the magnetic field increases the blood flow of at least one of the cortex and a lower region of the brain.

With respect to Claim 12, as amended, therefore, neither Souder nor Katz disclose or suggest "A system for treating depression in a subject comprising: a magnetic field generator adapted to apply a magnetic field to a head of the subject; wherein the magnetic field (a) moves an intrinsic frequency of a brain of the subject within a specified EEG band; (b) moves a Q-factor of the an intrinsic frequency; (c) moves a coherence value of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to a head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value; or (d) moves a EEG phase between two sites in the brain of the subject of a the specified EEG frequency, and wherein the magnetic field increases the blood flow of at least one of the cortex and a lower region of the brain."

In summary, both Souder and Katz fail to disclose or suggest all of the elements in the Claim 12 as amended, whether considered individually or in combination with each other or with any other reference. Thus, Applicants submit that independent Claim 12, as amended, and all claims dependent therefrom are in condition of allowance.

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⁴ *Id*.

CONCLUSION

In light of the remarks set forth above, Applicants believe that the pending claims are under condition for allowance. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit account No. 23-2415 (Attorney Docket No.35784-707.203).

Respectfully submitted,

Date: March 19, 2014 By: <u>/Kristin Havranek/</u>

Kristin Havranek Reg. No. 58,789

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Appl. No. 12/944,591

Response/Amdmt Date: June 9, 2014

RESPONSE TO FINAL OFFICE ACTION

Attorrney Docket No. 35784-707.203

PATENT

REMARKS

The following remarks are in response to the Examiner's Final Office Action dated April 7, 2014. Claims 12, 18-20 are amended. Support for claim amendments can be found in Para. [0450] at least, and the application as filed. Claims 1-22 are pending. Reconsideration is respectfully requested in light of the following remarks.

Claim Rejections - 35 USC § 112

Claims 12-22 were rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter which the inventor or a joint inventor regards as the invention.

Claim 12 was rejected for reciting "a head" in line 9. Applicants thank the Examiner's for the suggestion to cite "the head". Applicants have amended the claim as suggested, therefore, the rejection is moot. Withdrawal of such rejection is respectfully requested.

Claim Rejections – 35 USC § 102

Claims 12-17 were rejected under 35 U.S.C. 102(b) as being anticipated by 6,001,055 ("Souder").

Without conceding the appropriateness of the rejection, Applicants appreciate the Examiner's suggestion to obviate the alleged intended use by interpretation of certain claim language. Applicants have amended the claims as suggested in order to expedite examination. Furthermore, in the OA dated September 23,2013, Examiner stated "Souder does not explicitly disclose that the device is capable of influencing an intrinsic frequency of a brain of the subject within a specified EEG band, a Q-factor [o]f an intrinsic frequency of the brain of the subject within a specified EEG band, a coherence of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band, and an EEG phase between two sites in the brain of the subject of a specified EEG frequency", therefore, these claims are in condition of allowance.

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Appl. No. 12/944,591 Attorrney Docket No. 35784-707.203 Response/Amdmt Date: June 9, 2014 PATENT

RESPONSE TO FINAL OFFICE ACTION

Claims 12 and 18-22 were rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by US 6,488,617 ("Katz").

Applicants appreciate the Examiner's suggestion to obviate the alleged intended use by interpretation of certain claim language. Without conceding the appropriateness of the rejection, Applicants have amended the claims as suggested, therefore, the rejection is moot.

The device of Katz describes <u>a feedback system</u>, which <u>in real time</u>, tries to move a subject <u>from a current brain state into a desired brain state</u> via magnetic stimulation. Brain states targeted in Katz are categorized based on the level of alertness of the subject. (Col. 1, line 14 to 34). These states include sleep states associated with brain wave frequencies in the delta and theta ranges of 1.5 to 3.5 Hz and 3.5 to 7 Hz, respectively, a relaxed state associated with brain wave frequencies in the alpha range of 7.5 to 12.5 Hz, and an excited state associated with brain wave frequencies in the beta range of 12.5 to 20 Hz (*Id.*, *See also*, Col. 6, lines 16-35). Thus, each state of Katz is within a different EEG band, and Katz tries to move the subject from one state (in one band) to another state (in another band). At least the following distinctions can be made from the present claims.

Katz targets a desired brain <u>state</u>, which encompasses <u>a range</u> of frequenc<u>ies</u> in multiple EEG bands. Claim 12 of the present invention requires a device that is configured to move¹ an intrinsic frequenc<u>y</u>, not a state encompassing a range of frequenc<u>ies</u>. Further, movement of the intrinsic frequency of Claim 12 is within a <u>single</u> specified EEG band, and thus movement of the intrinsic frequency is within that single specified EEG band. In contrast, Katz' methods and devices move the subject's brain waves from one band to another, by teaching moving the subject from one brain state to a desired brain state. Brain states in Katz correlate to separate EEG bands in Katz (e.g. from relaxed in the alpha band to sleep in the delta or theta band).

Further, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject wherein the magnetic field

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¹ as a possible alternative to moving the Q-factor, coherence, or phase

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is configured to move a Q-factor of an intrinsic frequency of a brain of the subject within a specified EEG band as required in Claim 12.² As provided in the present application Figure 12, at least, and descriptions thereof, Q-factor is a measure of distribution around the intrinsic frequency within a single EEG band. Katz has no measurement or recognition of any such distribution around an intrinsic frequency, as it seeks to move brain states, without regard for any intrinsic frequency in a particular EEG band.

Likewise, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject wherein the magnetic field is configured to move a subject's coherence value required in Claim 12.3 Katz expresses a goal of achieving symmetry in magnitude of the EEG readings starting with asynchronous magnetic fields (0.5Hz, 5Hz) (see Col. 8, line 39-60, at least). Thus, any secondary preference toward coherent waves appears to also use asynchronous magnetic fields. (See, Column 8 line 39-60, at least). In contrast, the system of Claim 12 is configured to move⁴ a coherence value of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to a head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value.

Furthermore, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject wherein the magnetic field is configured to move an EEG phase between two sites in the brain of the subject of a specified EEG frequency.

Additionally, neither Katz nor Souder disclose or suggest comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject wherein the magnetic field is configured to increase the blood flow of at least one of the cortex and a lower region of the brain.

⁴ *Id*.

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² as a possible alternative to moving the intrinsic frequency, coherence, or phase

³ as a possible alternative to moving the intrinsic frequency, Q-factor, or phase

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In summary, both Souder and Katz fail to disclose or suggest all of the elements in the Claim 12 as amended, whether considered individually or in combination with each other or with any other reference. Withdrawal of this rejection and advancement of Claim 12 and all claims dependent thereon to allowance is respectfully requested.

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Appl. No. 12/944,591 Attorrney Docket No. 35784-707.203

Response/Amdmt Date: June 9, 2014 RESPONSE TO FINAL OFFICE ACTION

CONCLUSION

In light of the remarks set forth above, Applicants believe that the pending claims are under condition for allowance. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit account No. 23-2415 (Attorney Docket No. 35784-707.203).

Respectfully submitted,

Date: June 9, 2014 By: <u>/Kristin Havranek/</u>

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Appl. No. 12/944,591 Attorrney Docket No. 35784-707.203
Response/Amdmt Date: July 7, 2014

PATENT

RESPONSE TO FINAL OFFICE ACTION

REMARKS

The following remarks are in response to the Examiner's Final Office Action dated April 7, 2014 and Advisory Action dated June 19, 2014. Claims 12, 18-20 are amended. Support for claim amendments can be found in Paragraphs [0342], [0450], [459] to [463], and [468], at least, and the application as filed. Claims 1-11 (previously withdrawn) are cancelled. Claims 12-22 are pending. Reconsideration is respectfully requested in light of the following remarks.

Claim Rejections - 35 USC § 112

Claims 12-22 were rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as allegedly being indefinite for failing to particularly point and distinctly claim the subject matter which the inventor or a joint inventor regards as the invention.

Claim 12 was rejected for reciting "a head" in line 9. Applicants thank the Examiner's for the suggestion to cite "the head". Applicants have amended the claim as suggested, therefore, the rejection is moot. Withdrawal of such rejection is respectfully requested.

Claims 12-22 as presented in the response to the Examiner's Final Office Action dated April 7, 2014 were noted in the Advisory Action dated June 19, 2014 as allegedly missing essential elements. Without conceding the appropriateness of the rejection, Applicants have amended Claim 12 in order to clarify how the magnetic field is configured to perform the claimed functions and expedite examination; therefore, the rejection is moot. Withdrawal of such rejection is respectfully requested.

Claim Rejections – 35 USC § 102

Claims 12-17 were rejected under 35 U.S.C. 102(b) as being anticipated by 6,001,055 ("Souder").

Without conceding the appropriateness of the rejection, Applicants appreciate the Examiner's suggestion to obviate the alleged intended use rejection; and applicants have

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PATENT

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amended the claims as suggested in order to expedite examination, therefore, the rejection is moot. Withdrawal of such rejection is respectfully requested.

Claims 12 and 18-22 were rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by US 6,488,617 ("Katz").

Applicants appreciate the Examiner's suggestion in the Final Office Action dated April 7, 2014 to obviate the alleged intended use by interpretation of certain claim language. Applicants also thank Examiner for the suggestion of amending parts (a) and (b) of claim 12 in the Advisory Action dated June 19, 2014. Without conceding the appropriateness of the rejection, Applicants have amended the claims to address Examiner's points, therefore, Applicants believe the rejection of Claim 12 and 18-22 is obviated by such amendments.

The device of Katz describes <u>a feedback system</u>, which <u>in real time</u>, tries to move a subject <u>from a current brain state into a desired brain state</u> via magnetic stimulation. Brain states targeted in Katz are categorized based on the level of alertness of the subject. (Col. 1, line 14 to 34). These states include sleep states associated with brain wave frequencies in the delta and theta ranges of 1.5 to 3.5 Hz and 3.5 to 7 Hz, respectively, a relaxed state associated with brain wave frequencies in the alpha range of 7.5 to 12.5 Hz, and an excited state associated with brain wave frequencies in the beta range of 12.5 to 20 Hz (*Id.*, *See also*, Col. 6, lines 16-35). Thus, each state of Katz is within a different EEG band, and Katz tries to move the subject from one state (in one band) to another state (in another band). At least the following distinctions can be made from the present claims.

Katz targets a desired brain <u>state</u>, which encompasses <u>a range</u> of frequenc<u>ies</u> in multiple EEG bands. Claim 12 of the present invention requires a device that is configured to move¹ an intrinsic frequenc<u>y</u>, not a state encompassing a range of frequenc<u>ies</u>. Further, movement of the intrinsic frequency of Claim 12 is within a <u>single</u> specified EEG band in a preselected direction, up or down, and thus movement of the intrinsic frequency is only within that single specified EEG band and only in a pre-selected direction, up or down (support in Paragraph

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¹ as a possible alternative to moving the Q-factor, coherence, or phase

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[459]). In contrast, Katz' methods and devices move the subject's brain waves from one band to another, by teaching moving the subject from one brain state to a desired brain state. Brain states in Katz correlate to separate EEG bands in Katz (e.g. from relaxed in the alpha band to sleep in the delta or theta band).

Further, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject, wherein the magnetic field generator comprises information comprising a Q factor of an intrinsic frequency of a brain of the subject and a processor that controls the magnetic field and wherein the magnetic field is configured to move the Q-factor in a pre-selected direction, up or down, within a specified EEG band using said magnetic field as required in Claim 12.² As provided in the present application Figure 12, at least, and descriptions thereof, Q-factor is a measure of distribution around the intrinsic frequency within a single EEG band. Katz has no measurement or recognition of any such distribution around an intrinsic frequency, as it seeks to move brain states, without regard for any intrinsic frequency in a particular EEG band.

Likewise, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject, wherein the magnetic field generator comprises information comprising a coherence value of two intrinsic frequencies, wherein the two intrinsic frequencies are from two different sites in the brain of the subject within the specified EEG band and a processor that controls the magnetic field, and wherein the magnetic field is configured to move the coherence value required in Claim 12. Katz expresses a goal of achieving *symmetry in magnitude* of the EEG readings starting with asynchronous magnetic fields (0.5Hz, 5Hz) (see Col. 8, line 39-60, at least). Thus, any *secondary* preference toward coherent waves appears to also use *asynchronous magnetic fields*. (See, Column 8 line 39-60, at least). In contrast, the system of Claim 12 is configured to move⁴ the coherence value by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to a head of the subject

⁴ *Id*.

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² as a possible alternative to moving the intrinsic frequency, coherence, or phase

³ as a possible alternative to moving the intrinsic frequency, Q-factor, or phase

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and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value.

Furthermore, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject, wherein the magnetic field generator comprises information comprising an EEG phase between two different sites in the brain of the subject of a specified EEG frequency and a processor that controls the magnetic field and wherein the magnetic field is configured to move the EEG phase.

Additionally, neither Katz nor Souder disclose or suggest comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject, wherein the magnetic field generator comprises information and a processor that controls the magnetic field and wherein the magnetic field is configured to increase the blood flow of at least a cortex of the brain or decrease the blood flow of a lower region of the brain.

In summary, both Souder and Katz fail to disclose or suggest all of the elements in the Claim 12 as amended, whether considered individually or in combination with each other or with any other reference. Withdrawal of this rejection and advancement of Claim 12 and all claims dependent thereon to allowance is respectfully requested.

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Appl. No. 12/944,591 Attorrney Docket No. 35784-707.203

Response/Amdmt Date: July 7, 2014 RESPONSE TO FINAL OFFICE ACTION

CONCLUSION

In light of the remarks set forth above, Applicants believe that the pending claims are under condition for allowance. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit account No. 23-2415 (Attorney Docket No. 35784-707.203).

Respectfully submitted,

Date: July 7, 2014 By: /Kristin Havranek/

Kristin Havranek Reg. No. 58,789 **PATENT**

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ELECTRONICALLY FILED ON MARCH 19, 2014

Attorney Docket No. 35784-707.203
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: James William Phillips, et al.

Serial Number: 12/944,591

Filing Date: November 11, 2010

Title: SYSTEMS AND METHODS FOR

DEPRESSION TREATMENT USING NEURO-EEG SYNCHRONIZATION

THERAPY

Group Art Unit: 3735

Examiner: Lannu, Joshua

Confirmation No: 6039

Customer No. 21971

RESPONSE TO OFFICE ACTION

MAIL STOP AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450

Commissioner:

This paper is in response to Examiner's Office Action mailed September 23, 2013. The shortened statutory period for response expired on December 23, 2013. Applicants therefore request Extension of Time for filing a reply within the third month and the fee set forth under 37 C.F.R. §1.17(a)(3) is electronically submitted herewith.

Applicants respectfully request reconsideration of the above-referenced application in view of the following amendments and remarks.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 6 of this paper.

Conclusion begins on page 10 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings of claims in this application. Applicant reserves the right to pursue any subject matter of any canceled claims in this or any other appropriate patent application. Support for these claims is provided in the remarks following the listing of claims.

- 1. (Withdrawn- Currently Amended) A method for treating depression in a subject comprising:
 - (a) adjusting output of a magnetic field generator for influencing—at least one of an intrinsic frequency of a specified EEG band of the subject toward a pre-selected intrinsic frequency of the specified EEG band and—a Q-factor of an intrinsic frequency within a specified EEG band of a subject toward a pre-selected Q-factor and
 - (b) applying said a magnetic field generated by the magnetic field generator close to a head of the subject;
 - thereby moving an intrinsic frequency of a brain of the subject within a specified EEG band or moving a Q-factor of the intrinsic frequency, wherein the pre-selected intrinsic frequency is a frequency that moving the intrinsic frequency or the Q-factor increases blood flow in the cortex of the subject, and wherein the pre-selected Q-factor is a Q-factor that increases blood flow in the cortex of the subject.
- 2. (Withdrawn- Currently Amended) A method for treating depression in a subject comprising:
 - (a) adjusting output of a magnetic field generator for influencing an intrinsic frequency of a specified EEG band of a subject toward a pre-selected intrinsic frequency of the specified EEG band; and
 - (b) applying said a magnetic field generated by the magnetic field generator elose to a head of the subject;

thereby moving an intrinsic frequency of a brain of the subject within a specified EEG band or moving a Q-factor of the intrinsic frequency, wherein moving the intrinsic frequency or the Q-factor the pre-selected intrinsic frequency is a frequency that decreases blood flow in a lower region of the brain of the subject.

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- 3. (Withdrawn- Currently Amended) The method of any <u>one</u> of claims 1 and 2, further comprising taking EEG measurements of the subject before the adjusting step or after the applying step, or both before the adjusting step and after the applying step.
- 4. (Withdrawn- Currently Amended) The method of any <u>one</u> of claims 1 and 2, further comprising determining at least one of: the subject's intrinsic frequency of the specified EEG band and the subject's Q-factor of an intrinsic frequency within a specified EEG band.
- 5. (Withdrawn- Currently Amended) The method of any <u>one</u> of claims 1 and 2, wherein the applying of the magnetic field applies the magnetic field to a diffuse area in a brain of the subject.
- 6. (Withdrawn- Currently Amended) The method of any <u>one</u> of claims 1 and 2, wherein the magnetic field is generated by movement of at least one permanent magnet.
- 7. (Withdrawn- Currently Amended) The method of claim <u>6</u> 8, wherein the strength of the at least one permanent magnetic is from about 10 Gauss to about 4 Tesla.
- 8. (Withdrawn- Currently Amended) The method of any <u>one</u> of claims 1 and 2, wherein the step of applying the magnetic field is for about 5 minutes to about two hours.
- 9. (Withdrawn- Currently Amended) The method of any <u>one</u> of claims 1 and 2, further comprising repeating the applying step after an interval about 6 hours to about 14 days.
- 10. (Withdrawn- Currently Amended) The method of any <u>one</u> of claims 1 and 2, further comprising: (a) locating a first electrode operable to detect electrical brain activity on the subject in at least one of an area of low electrical resistivity on <u>a the</u> subject, and an area with substantially no electrical impulse interference on <u>a the</u> subject; (b) locating a second electrode operable to detect a reference signal on the subject; and (c) determining the intrinsic frequency or the Q-factor or both from the electrical brain activity detected by the first electrode and the reference signal detected by the second electrode.
 - 11. (Withdrawn- Currently Amended) The method of any <u>one</u> of claims 1 and 2, wherein the method provides an improvement as measured using a HAMD rating scale.(Original)
 - 12. (Currently Amended) A system for treating depression in a subject comprising:

 a means magnetic field generator for applying adapted to apply a magnetic field to a head of the subject; whereby wherein the means for applying the magnetic field is capable of influencing at least one of: (a) moves an intrinsic frequency of a brain of the subject

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within a specified EEG band; (b) <u>moves</u> a Q-factor of <u>the an</u> intrinsic frequency of the brain of the subject within a specified EEG band; (c) <u>moves</u> a coherence <u>value</u> of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to a head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value; and or (d) moves a EEG phase between two sites in the brain of the subject of a <u>the specified EEG</u> frequency, and wherein the magnetic field increases the blood flow of cortex of the brain or decreases the blood flow of a lower region of the brain and a device capable of determining the blood flow of at least one of the cortex and a lower region of the brain.

- 13. (Previously Presented) The system of claim 12, comprising at least one permanent magnet.
- 14. (Previously Presented) The system of claim 12, wherein the magnetic field is generated by movement of at least one permanent magnet.
- 15. (Currently Amended) The system of claim [[12]] 14, wherein the movement of the at least one said magnet is at a frequency between about 0.5 Hz and about 100 Hz.
- 16. (Currently Amended) The system of claim [[12]] <u>14</u>, wherein said movement comprises at least one of rotational motion, linear motion, and swing motion.
- 17. (Currently Amended) The system of claim [[12]] <u>14</u>, wherein said movement generates an alternating magnetic field.
- 18. (Currently Amended) The system of claim 12, further comprising logic that controls the intrinsic frequency to be any intrinsic frequency between about 0.5 Hz and about 100 Hz in increments of about 0.1 Hz.
- 19. (Currently Amended) The system of claim 12, further comprising logic that automatically changes the <u>intrinsic frequency</u> in response to EEG readings of a subject during treatment.
- 20. (Previously Presented) The system of claim 12, further comprising logic that calculates information from EEG data collected from the subject within a specified EEG band, wherein said information comprises at least one of items listed below: (a) at least one

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- intrinsic frequency; (b) Q-factor of the at least one intrinsic frequency; (c) a coherence value of intrinsic frequencies; (d) an EEG phase; and (e) any combination thereof.
- 21. (Currently Amended) The system of claim 12, further comprising: (a) a first electrode operable to detect electrical brain activity; and (b) a second electrode operable to detect a reference signal; wherein the first electrode is <u>adapted to be</u> located on the subject in at least one of: an area of low electrical resistivity on <u>a said</u> subject, and an area with substantially no electrical impulse interference on <u>a said</u> subject, and wherein the second electrode is <u>adapted to be</u> located on the subject.
- 22. (New) The system of claim 12, further comprising a device configured to measure blood flow of at least one of the cortex and a lower region of the brain.

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REMARKS

The following remarks are in response to the Examiner's Office Action mailed on September 23, 2013. Claims 12, 15-19 and 21 are amended. Claim 22 is new. Previously withdrawn claims 1-11 are amended in kind with the amendments to elected claims 12-22 herein, in order to support potential rejoinder, as appropriate. Support for claim amendments and new claims can be found in the application as filed. See, *e.g.*, paragraphs paras [0152], [0164], [277], [0295], [0357], or [0560], at least. Reconsideration is respectfully requested in light of the following remarks.

Claim Rejections - 35 U.S.C. § 112 (Pre-AIA) Second Paragraph

Claims 15-19 and 21 were rejected under 35 U.S.C. § 112 (pre-AIA) second paragraph as being indefinite.

Applicants have amended Claims 15-17, as suggested by the Examiner, to depend from Claim 14, which provides antecedent basis for the limitations "the movement" and/or "said movement." Withdrawal of the rejection of Claims 15-17 under 35 U.S.C. § 112 (pre-AIA) second paragraph is appropriate and respectfully requested.

Applicants have amended Claims 18 and 19 for clarification to indicate the "intrinsic" frequency. Withdrawal of the rejection of Claims 18-19 under 35 U.S.C. § 112 (pre-AIA) second paragraph is appropriate and respectfully requested.

Applicants have amended Claim 21, to specify "said subject". Withdrawal of Claim 21 under 35 U.S.C. § 112 (pre-AIA) second paragraph is appropriate and respectfully requested.

Claim Rejections - 35 U.S.C. § 101

Claim 21 was rejected under 35 U.S.C. § 101 (pre-AIA and post-AIA) and section 33(a) of the AIA as being directed to or encompassing a human organism. Applicants thank the Examiner for the suggestion to amend the claim to recite "wherein the first electrode is adapted to be located on the subject" and "wherein the second electrode is adapted to be

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located on the subject". Withdrawal of the rejection of Claim 21 under 35 U.S.C. § 101 (pre-AIA and post-AIA) and section 33(a) of the AIA is appropriate and respectfully requested.

Claim Rejections - 35 U.S.C. § 103

Claims 12-21 are rejected under pre-AIA 35 U.S.C. § 103(a) as being obvious over US 6,001,055 (Souder) and in view of US 6,488,617 (Katz). Applicants traverse, for at least the reasons stated below.

To establish a *prima facie* case of obviousness, the cited art itself or "the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]" at the time of the invention are to have taught or suggested the claim elements. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007); *See also* MPEP § 2143.03. Thus, the Examiner must make "a searching comparison of the claimed invention – including all its limitations – with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995). As such, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

The Office Action indicates that Souder fails to disclose or suggest multiple elements of Claim 12. Specifically, the Office Action states "Souder does not explicitly disclose that the device is capable of influencing an intrinsic frequency of a brain of the subject within a specified EEG band, a Q-factor [o]f an intrinsic frequency of the brain of the subject within a specified EEG band, a coherence of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band, and an EEG phase between two sites in the brain of the subject of a specified EEG frequency." Rather, the Office Action cites Katz for these elements. On the contrary, Katz fails to disclose or suggest any of these elements as filed, or as amended (for clarification).

The device of Katz describes <u>a feedback system</u>, which <u>in real time</u>, tries to move a subject <u>from a current brain state into a desired brain state</u> via magnetic stimulation. Brain states targeted in Katz are categorized based on the level of alertness of the subject. (Col. 1, line 14 to 34). These states include sleep states associated with brain wave frequencies in the delta and theta ranges of 1.5 to 3.5 Hz and 3.5 to 7 Hz, respectively, a relaxed state associated with brain wave frequencies in the alpha range of 7.5 to 12.5 Hz, and an excited

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state associated with brain wave frequencies in the beta range of 12.5 to 20 Hz (*Id., See also*, Col. 6, lines 16-35). Thus, each state of Katz is within a different EEG band, and Katz tries to move the subject from one state (in one band) to another state (in another band). At least the following distinctions can be made from the present claims.

Katz targets a desired brain <u>state</u>, which encompasses <u>a range</u> of frequencies in multiple bands. Claim 12 of the present invention requires moving an intrinsic frequency, not a state encompassing a range of frequencies. Further, movement of the intrinsic frequency of Claim 12 is within a <u>single</u> specified EEG band, and thus movement of the intrinsic frequency is within that single specified EEG band. In contrast, Katz' methods and devices move the subject's brain waves from one band to another, by teaching moving the subject from one brain state to a desired brain state. Brain states in Katz correlate to separate EEG bands in Katz (e.g. from relaxed in the alpha band to sleep in the delta or theta band).

Further, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject wherein the magnetic field moves a Q-factor of an intrinsic frequency of a brain of the subject within a specified EEG band as required in Claim 12.² As provided in the present application Figure 12, at least, and descriptions thereof, Q-factor is a measure of distribution around the intrinsic frequency within a single EEG band. Katz has no measurement or recognition of any such distribution around an intrinsic frequency, as it seeks to move brain states, without regard for any intrinsic frequency in a particular EEG band.

Likewise, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject wherein the magnetic field moves a subject's coherence value required in Claim 12.³ Katz expresses a goal of achieving **symmetry in magnitude** of the EEG readings starting with asynchronous magnetic fields (0.5Hz, 5Hz) (see Col. 8, line 39-60, at least). Thus, any **secondary** preference toward coherent waves appears to also use **asynchronous magnetic fields**. (See,

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¹ as a possible alternative to moving the O-factor, coherence, or phase

² as a possible alternative to moving the intrinsic frequency, coherence, or phase

³ as a possible alternative to moving the intrinsic frequency, Q-factor, or phase

Column 8 line 39-60, at least). In contrast, Claim 12 requires⁴ moving a coherence value of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to a head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value.

Furthermore, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject wherein the magnetic field moves an EEG phase between two sites in the brain of the subject of a specified EEG frequency.

Finally, neither Katz nor Souder disclose or suggest comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject wherein the magnetic field increases the blood flow of at least one of the cortex and a lower region of the brain.

With respect to Claim 12, as amended, therefore, neither Souder nor Katz disclose or suggest "A system for treating depression in a subject comprising: a magnetic field generator adapted to apply a magnetic field to a head of the subject; wherein the magnetic field (a) moves an intrinsic frequency of a brain of the subject within a specified EEG band; (b) moves a Q-factor of the an intrinsic frequency; (c) moves a coherence value of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to a head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value; or (d) moves a EEG phase between two sites in the brain of the subject of a the specified EEG frequency, and wherein the magnetic field increases the blood flow of at least one of the cortex and a lower region of the brain."

In summary, both Souder and Katz fail to disclose or suggest all of the elements in the Claim 12 as amended, whether considered individually or in combination with each other or with any other reference. Thus, Applicants submit that independent Claim 12, as amended, and all claims dependent therefrom are in condition of allowance.

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⁴ *Id*.

CONCLUSION

In light of the remarks set forth above, Applicants believe that the pending claims are under condition for allowance. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit account No. 23-2415 (Attorney Docket No.35784-707.203).

Respectfully submitted,

Date: March 19, 2014 By: __/Kristin Havranek/_

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21971 7590 09/25/2013 WILSON, SONSINI, GOODRICH & ROSATI 650 PAGE MILL ROAD PALO ALTO, CA 94304-1050			EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Case 5:23-cv-00626-XR Docume	ent 29-8 Filed 04/19/24	Page 29			
	Application No. 12/237,304	Applicant(s) PHILLIPS ET AL.			
Office Action Summary	Examiner STEPHEN GUCKER	Art Unit 1649	AIA (First Inventor to File) Status No		
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orresponden	ce address		
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	J. nely filed the mailing date c ⊃ (35 U.S.C. § 13	of this communication.		
Status					
1) Responsive to communication(s) filed on <u>20 De</u> A declaration(s)/affidavit(s) under 37 CFR 1.1 :	30(b) was/were filed on				
<i>'</i> =	action is non-final.				
An election was made by the applicant in response to a restriction requirement set forth during the interview on; the restriction requirement and election have been incorporated into this action. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E	•				
Disposition of Claims					
5) Claim(s) 1-35 is/are pending in the application. 5a) Of the above claim(s) 1-15 is/are withdrawn 6) Claim(s) is/are allowed. 7) Claim(s) 16-35 is/are rejected. 8) Claim(s) is/are objected to. 9) Claim(s) are subject to restriction and/or are subject to restriction and/or and the first any claims have been determined allowable, you may be eliminated intellectual property office for the corresponding aphttp://www.uspto.gov/patents/init_events/pph/index.jsp or send	election requirement. gible to benefit from the Patent Pros pplication. For more information, plea	se see	ıway program at a		
10) The specification is objected to by the Examiner.					
11) The drawing(s) filed on <u>24 September 2008</u> is/a Applicant may not request that any objection to the c Replacement drawing sheet(s) including the correction	drawing(s) be held in abeyance. See	37 CFR 1.85	(a).		
Priority under 35 U.S.C. § 119					
12) ☐ Acknowledgment is made of a claim for foreign Certified copies: a) ☐ All b) ☐ Some * c) ☐ None of the: 1. ☐ Certified copies of the priority documents 2. ☐ Certified copies of the priority documents 3. ☐ Copies of the certified copies of the priority documents application from the International Bureau * See the attached detailed Office action for a list of the copies: a) ☐ All b) ☐ Some c) ☐ None of the: Intering the copies is a compared to the certified copies.	s have been received. s have been received in Applicat rity documents have been receive (PCT Rule 17.2(a)). the certified copies not received.	ion No ed in this Na	tional Stage		
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Attachment(s) 1) Notice of References Cited (PTO-892)	3) Interview Summary				
2) Information Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Da 4)	ate			

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Response to Amendment

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1. The present application is being examined under the pre-AIA first to invent provisions.

2. Responsive to Applicant's amendment filed 12/20/12, all provisional rejections of obviousness-type double patenting are withdrawn due to the filing of terminal disclaimers over 12/237,319 (now US 8,475,354); 12/237,295; 12/237,328 (now US 8,480,554); and 12/850,547 (now US 8,465,408). Furthermore, the 35 USC 112, 2nd paragraph rejection of record is also withdrawn due to Applicant's amendment to the claims. New rejections under 35 USC 112, 1st and 2nd paragraphs necessitated by Applicant's amendment are set forth below. All prior art rejections of record are also maintained.

3. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n).

- **4.** Claims 31-33 and 35 are objected to for being dependent on a higher numbered claim.
- The following is a quotation of 35 U.S.C. 112(a):(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), first paragraph:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- Claims 27 and 35 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for pre-AIA the inventor(s), at the time the application was filed, had possession of the claimed invention.

 Claims 27 and 35 recite the phrase "tunes up the Q-factor" which is not found verbatim in the instant specification as filed. Furthermore, the use of the word "tune" in the disclosure is limited to paragraphs 0004, 0162, and 0353 which describe gently tuning the brain to affect mood, etc., or to tune an intrinsic frequency (of the patient's alpha wave). Accordingly, the specific concept of "tunes up the Q-factor" does not flow readily from the specification, particularly when Q-factor is described as a measure of frequency selectivity of a specified EEG band of the subject toward a pre-selected or target Q-factor of the band (paragraph 007). This is a new matter rejection.
- 7. The following is a quotation of 35 U.S.C. 112(b):

 (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 27, 30-33, and 35 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention. Claims 27 and 35 recite "tunes up the Q-factor" by applying a single or a plurality of frequencies. While applying a frequencie(s) may produce an observable effect, "tunes up the Q-factor" is completely subjective in the context of the instant invention. Also, claim 35 is the highest numbered pending claim, yet it is dependent upon claim 38.

Claim 30 recites a second permanent magnet wherein the subunit is coupled to the second magnet. However, claim 26 upon which claim 30 depends recites that the subunit is coupled to the magnet which refers to the at least one permanent magnet as recited by claim 26. It is vague and unclear if the subunit can be coupled to one permanent magnet and then coupled to a second permanent magnet, or if multiple subunits are coupled to separate magnets. Claims 31-32 recite first and second permanent magnets that lack antecedent basis in claim 34 on which they depend, rendering the claims indefinite. Claim 33 depends upon claim 35 which lacks antecedent basis for claim 33 rendering claim 33 indefinite.

9. The following is a quotation of the appropriate paragraphs of pre-AIA 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

⁽b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. Claims 16, 20, 23-25, and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,488,617 (reference 8 of IDS filed 1/25/09, "Katz") for reasons of record and the following. Katz teaches a device with magnetic stimulation and EEG recording capabilities to produce a desired brain state.

In regards to claim 16, Katz discloses a device that influences EEG frequencies in the brain by applying a magnetic field close to the head of a subject. Furthermore, Katz teaches that said device can be used for producing a greater degree of relaxation (patented claim 16).

In regards to claim 20, the magnets of the device can be moved along elements 9 and 10 by the computational system via a small motor (column 7 lines 1-18).

In regards to claims 23-25 and 34-35, Katz states that the invention disclosed executes steps to influence intrinsic frequencies of EEG bands to a desired state via magnetic stimulation (column 6 lines 16-61) by an algorithm that is executed by a computational system that adjusts parameters of magnetic stimulation until the distance between the desired EEG signal and the actual EEG signal is minimized (column 7 lines 26-63). Katz also shows in Figure 2 a system with magnets that apply the magnetic field to the head of the subject (column 6 line 62 – column 7 line 18) and frequencies of 0.5 Hz and 5 Hz for low and high frequency magnets (column 8 lines 39-46). Katz further states that the method of the device is used to induce relaxation by increasing the magnitude of the alpha rhythm and by increasing synchronization between the left and right hemispheres (column 4 lines 15-18).

In regards to claims 16, 24, and 34-35, Q-factor is being interpreted as the bandwidth about a center frequency. Katz states that a higher magnitude magnetic field increases the focus of a mean frequency, which is the equivalent of modifying the bandwidth of an intrinsic

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frequency to a preselected bandwidth (column 6 lines 16-61). Additionally, coherence is defined as waves with the same frequency and in phase. Katz discloses a device that influences EEG frequencies in the brain by applying a magnetic field close to the head of a subject by stimulation along multiple sites in a brain of a subject (Figure 2). Katz shows the device stimulating multiple sites in Figure 2 as well as influencing coherence from multiple sites in the brain to get to a state of relaxation, which is correlated to the strength of the alpha band (column 8 line 39 to column 9 line 16).

In regards to claim 25, electrodes are shown in Figure 1 (also column 5 lines 20-49). All the electrodes are operable to detect brain activity. If one electrode is chosen as the one for detecting brain activity, any of the other electrodes can function as a second electrode to detect a reference signal. Katz shows EEG comparisons to determine coherence between the left and right hemispheres (column 8 lines 39-59), which in essence is a difference or correlation between a signal and a reference signal. Electrical resistivity is the measure of how strongly a material opposes the flow of electric current. Because all the electrodes are on skin, which allows electric current to flow, the electrodes would be on an area of low electrical resistivity. Electrical impulse interference is essentially noise. Additionally, because the electrodes are on the scalp, the electrodes are in an area with substantially no electrical impulse activity due to the electrical signals being mostly coming from neurons instead of other sources such as eye muscles. Katz states that having feedback with the therapy allows for the minimization of differences between an actual and desired brain state (see abstract).

Applicant's arguments filed 12/20/12 have been fully considered but they are not persuasive because Applicant argues that Katz fails to teach a means for applying a magnetic

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field to a head of the subject...[that] "comprises logic that moves" (part of the amendment to claim 16 filed 12/20/12) at least one of (a) or (b) or (c) or (d) (see claim 16). As the record above demonstrates, Katz teaches that the magnets of the prior art device can be moved along elements 9 and 10 by the computational system via a small motor (column 7 lines 1-18). Furthermore, Katz states that the invention disclosed executes steps to influence intrinsic frequencies of EEG bands to a desired state via magnetic stimulation (column 6 lines 16-61) by an algorithm that is executed by a computational system that adjusts parameters of magnetic stimulation until the distance between the desired EEG signal and the actual EEG signal is minimized (column 7 lines 26-63). It is the Examiner's position that the computational system of Katz meets the amended claim limitation of "comprises logic that moves" absent evidence to the contrary, because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Also see the instant specification at paragraphs 0047, 0050, 0056-0057, 0063-0064, 0266, and 0361 that describe "logic" as any hardware, software, or computer readable format that controls and automatically changes the frequency, calculates information from EEG data, uploads information, downloads a treatment dosage quota, records usage information for the device, allows a user to establish a user account, receives and records EEG signal prior to and/or following application of the magnetic field, determines the intrinsic frequency of a specified EEG band of the subject using the EEG signal prior to and/or following application of the magnetic field to the subject's brain, etc.

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With regards to Applicant's arguments drawn to Katz targeting a desired brain state encompassing a range of frequencies and moving a subject from a current brain state into a desired brain state or moving brain waves from one band to another, these arguments are unpersuasive because they amount to intended uses of the prior art device which cannot be used to distinguish it from the instant invention as previously noted without a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. It is noted that Applicant's arguments are repeatedly drawn to how the instant invention is used differently from the prior art and not how the instant invention is constructed differently from the prior art.

- **11.** The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- **12.** The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 16-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,001,055 (reference 15 of IDS filed 1/25/09, "Souder") in view of Katz for reasons of record and the following.

In regards to claims 17-19, 21-22, and 26-35, Souter discloses a device that is used for magnetic therapy. The device extends a magnetic field for application to an anatomical area (see abstract). Souder discloses several device embodiments made of at least one permanent magnet (element 24, column 6 lines 14-16) and a subunit coupled to the magnet that allows the magnet to rotate in a rotational motion (column 6 lines 37-39) such as element 20 in Figure 3. Souder states that a moving magnetic field is generated by the rotation of the permanent magnet and subjects the treatment area to varying intensities of north or south pole fields (column 6 lines 1-36). Souder also states that the user is subjected to alternating magnetic fields (column 10 lines 9-15). Souder mentions the concept of making an alternating magnetic field as moving magnets relative to a treatment area (column 5 lines 58-61). Souder also states that the speeds at which the shafts spin the magnets are preferably between 400 - 8000 revolutions per minute (RPMs), which based on RPM to Hz conversions would be between 6.66 Hz and 133.33 Hz (column 8 lines 17-32) which overlaps in the range specified by Applicant. In addition, Souter states that the device is capable of going to lower frequencies as dictated to get to an optimal frequency (column 8 lines 30-32), which would enable movement to the 0.5 Hz frequency. Also, the device of Souter comprises multiple rotating magnets (col 7 line 60 to col 8 line 57; see Figures 9-12).

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Elements 20 and 26 of Fig. 12 of Souter also meet the limitation of a subunit connected to the magnets (also see element 20 as depicted in Fig. 5 and see Fig. 4 for motor and power source claim elements). With regards to claim 31, Souter meets the limitations of this claim because said first and second rotational orientations relative to the treatment surface can be the same or equal (the claim does not exclude this possibility). With regards to claim 32, the device of Fig. 12 of Souter is operable to move the first and second magnets with the same frequency because the magnets are coupled to the same rotating surface. With regards to claim 33, Fig. 12 of Souter meets the limitations of this claim at least because the rotational orientations can be different by about 0 degrees, i.e., no difference. However, Souder does not explicitly state that the device is capable of influencing an intrinsic frequency of a brain of the subject within a specified EEG band, a Q-factor if an intrinsic frequency of a brain of the subject within a specified EEG band, a coherence of intrinsic frequencies among multiple sites in a brain of a subject of a specified EEG band, and a phase between two sites in the brain of a subject of a specified EEG frequency. Neither does Souter explicitly teach a device further comprising a logic that controls the frequencies in increments of about 0.1 Hz. The teachings of Katz are as set forth above concerning Q-factors, intrinsic frequencies, logic, and coherence between multiple brain sites. Katz teaches the logic (element 7) that controls frequency stimulation. Because the logic is depicted as a computer, it would be capable of controlling frequencies by increments of 0.1 Hz. Katz includes this feature in his system to influence these EEG frequencies and allow improvement of deficient or non-optimal mental states (column 1 lines 57-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a logic to change magnetic stimulation frequencies and calculate EEG information and influence

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EEG data as taught by Katz into the device disclosed by Souder in order to influence EEG frequencies and allow improvement of deficient and non-optimal mental states, particularly to increase relaxation as disclosed by Katz.

Applicant's arguments filed 12/20/12 have been fully considered but they are not persuasive because Applicant argues Souter in isolation and states that Katz fails to disclose the elements of claim 16. This argument is not convincing because Katz teaches that the magnets of the prior art device can be moved along elements 9 and 10 by the computational system via a small motor (column 7 lines 1-18). Furthermore, Katz states that the invention disclosed executes steps to influence intrinsic frequencies of EEG bands to a desired state via magnetic stimulation (column 6 lines 16-61) by an algorithm that is executed by a computational system that adjusts parameters of magnetic stimulation until the distance between the desired EEG signal and the actual EEG signal is minimized (column 7 lines 26-63). It is the Examiner's position that the computational system of Katz meets the amended claim limitation of "comprises logic that moves" absent evidence to the contrary, because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

15. No claim is allowed.

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16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is 571-272-0883. The examiner can normally be reached on Mondays through Fridays from 0930 to 1800.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. G./

Examiner, Art Unit 1649

Stephen Gucker

September 24, 2013

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649

ELECTRONICALLY FILED ON JUNE 9, 2014

Attorney Docket No. 35784-707.203 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: James William Phillips, et al.

Serial Number: 12/944,591

Filing Date: November 11, 2010

Title: SYSTEMS AND METHODS FOR

DEPRESSION TREATMENT USING NEURO-EEG SYNCHRONIZATION

THERAPY

Group Art Unit: 3735

Examiner: Lannu, Joshua

Confirmation No: 6039

Customer No. 21971

RESPONSE TO FINAL OFFICE ACTION

MAIL STOP AF Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450

Commissioner:

This paper responds to the Final Office Action dated April 7, 2014 setting an initial due date of July 7, 2014, with a two month Advisory Action deadline of June 7, 2014. Therefore, Applicants believe that this response is being timely filed. Applicants believe no fees are due with this submission.

Applicants respectfully request reconsideration of the above-referenced application in view of the following amendments and remarks.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 6 of this paper.

Conclusion begins on page 10 of this paper.

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AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings of claims in this application. Applicant reserves the right to pursue any subject matter of any canceled claims in this or any other appropriate patent application. Support for these claims is provided in the remarks following the listing of claims.

- 1. (Withdrawn- Previously Presented) A method for treating depression in a subject comprising:
 - (a) adjusting output of a magnetic field generator and
 - (b) applying a magnetic field generated by the magnetic field generator to a head of the subject;
 - thereby moving an intrinsic frequency of a brain of the subject within a specified EEG band or moving a Q-factor of the intrinsic frequency, wherein moving the intrinsic frequency or the Q-factor increases blood flow in the cortex of the subject.
- 2. (Withdrawn-Previously Presented) A method for treating depression in a subject comprising:
 - (a) adjusting output of a magnetic field generator and
 - (b) applying a magnetic field generated by the magnetic field generator to a head of the subject
 - thereby moving an intrinsic frequency of a brain of the subject within a specified EEG band or moving a Q-factor of the intrinsic frequency, wherein moving the intrinsic frequency or the Q-factor decreases blood flow in a lower region of the brain of the subject.
- 3. (Withdrawn- Previously Presented) The method of any one of claims 1 and 2, further comprising taking EEG measurements of the subject before the adjusting step or after the applying step, or both before the adjusting step and after the applying step.
- 4. (Withdrawn- Previously Presented) The method of any one of claims 1 and 2, further comprising determining at least one of: the subject's intrinsic frequency of the specified EEG band and the subject's Q-factor of an intrinsic frequency within a specified EEG band.

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5. (Withdrawn- Previously Presented) The method of any one of claims 1 and 2, wherein the applying of the magnetic field applies the magnetic field to a diffuse area in a brain of the subject.

- 6. (Withdrawn- Previously Presented) The method of any one of claims 1 and 2, wherein the magnetic field is generated by movement of at least one permanent magnet.
- 7. (Withdrawn- Previously Presented) The method of claim 6, wherein the strength of the at least one permanent magnetic is from about 10 Gauss to about 4 Tesla.
- 8. (Withdrawn- Previously Presented) The method of any one of claims 1 and 2, wherein the step of applying the magnetic field is for about 5 minutes to about two hours.
- 9. (Withdrawn- Previously Presented) The method of any one of claims 1 and 2, further comprising repeating the applying step after an interval about 6 hours to about 14 days.
- 10. (Withdrawn- Previously Presented) The method of any one of claims 1 and 2, further comprising: (a) locating a first electrode operable to detect electrical brain activity on the subject in at least one of an area of low electrical resistivity on the subject, and an area with substantially no electrical impulse interference on the subject; (b) locating a second electrode operable to detect a reference signal on the subject; and (c) determining the intrinsic frequency or the Q-factor or both from the electrical brain activity detected by the first electrode and the reference signal detected by the second electrode.
- 11. (Withdrawn- Previously Presented) The method of any one of claims 1 and 2, wherein the method provides an improvement as measured using a HAMD rating scale.
- 12. (Currently Amended) A system for treating depression in a subject comprising: a magnetic field generator adapted to apply a magnetic field to a head of the subject; wherein the magnetic field is configured to (a) moves move an intrinsic frequency of a brain of the subject within a specified EEG band; (b) moves move a Q-factor of the intrinsic frequency; (c) moves move a coherence value of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to a-the head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value; or (d) moves move an

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EEG phase between two sites in the brain of the subject of the specified EEG frequency, and wherein the magnetic field increases the blood flow of <u>a</u> cortex of the brain or decreases the blood flow of a lower region of the brain.

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- 13. (Previously Presented) The system of claim 12, comprising at least one permanent magnet.
- 14. (Previously Presented) The system of claim 12, wherein the magnetic field is generated by movement of at least one permanent magnet.
- 15. (Previously Presented) The system of claim 14, wherein the movement of the at least one said magnet is at a frequency between about 0.5 Hz and about 100 Hz.
- 16. (Previously Presented) The system of claim 14, wherein said movement comprises at least one of rotational motion, linear motion, and swing motion.
- 17. (Previously Presented) The system of claim 14, wherein said movement generates an alternating magnetic field.
- 18. (Previously Presented) The system of claim 12, further comprising logic that configured to controls the intrinsic frequency to be any intrinsic frequency between about 0.5 Hz and about 100 Hz in increments of about 0.1 Hz.
- 19. (Previously Presented) The system of claim 12, further comprising logic that configured to automatically changes the intrinsic frequency in response to EEG readings of a subject during treatment.
- 20. (Previously Presented) The system of claim 12, further comprising logic that configured to ealculate information from EEG data collected from the subject within a specified EEG band, wherein said information comprises at least one of items listed below: (a) at least one intrinsic frequency; (b) Q-factor of the at least one intrinsic frequency; (c) a coherence value of intrinsic frequencies; (d) an EEG phase; and (e) any combination thereof.
- 21. (Previously Presented) The system of claim 12, further comprising: (a) a first electrode operable to detect electrical brain activity; and (b) a second electrode operable to detect a reference signal; wherein the first electrode is adapted to be located on the subject in at least one of: an area of low electrical resistivity on said subject, and an area with

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substantially no electrical impulse interference on said subject, and wherein the second electrode is adapted to be located on the subject.

22. (Previously Presented) The system of claim 12, further comprising a device configured to measure blood flow of at least one of the cortex and a lower region of the brain.

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REMARKS

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The following remarks are in response to the Examiner's Final Office Action dated April 7, 2014. Claims 12, 18-20 are amended. Support for claim amendments can be found in Para. [0450] at least, and the application as filed. Claims 1-22 are pending. Reconsideration is respectfully requested in light of the following remarks.

Claim Rejections - 35 USC § 112

Claims 12-22 were rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter which the inventor or a joint inventor regards as the invention.

Claim 12 was rejected for reciting "a head" in line 9. Applicants thank the Examiner's for the suggestion to cite "the head". Applicants have amended the claim as suggested, therefore, the rejection is moot. Withdrawal of such rejection is respectfully requested.

Claim Rejections – 35 USC § 102

Claims 12-17 were rejected under 35 U.S.C. 102(b) as being anticipated by 6,001,055 ("Souder").

Without conceding the appropriateness of the rejection, Applicants appreciate the Examiner's suggestion to obviate the alleged intended use by interpretation of certain claim language. Applicants have amended the claims as suggested in order to expedite examination. Furthermore, in the OA dated September 23,2013, Examiner stated "Souder does not explicitly disclose that the device is capable of influencing an intrinsic frequency of a brain of the subject within a specified EEG band, a Q-factor [o]f an intrinsic frequency of the brain of the subject within a specified EEG band, a coherence of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band, and an EEG phase between two sites in the brain of the subject of a specified EEG frequency", therefore, these claims are in condition of allowance.

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Claims 12 and 18-22 were rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by US 6,488,617 ("Katz").

Applicants appreciate the Examiner's suggestion to obviate the alleged intended use by interpretation of certain claim language. Without conceding the appropriateness of the rejection, Applicants have amended the claims as suggested, therefore, the rejection is moot.

The device of Katz describes <u>a feedback system</u>, which <u>in real time</u>, tries to move a subject <u>from a current brain state into a desired brain state</u> via magnetic stimulation. Brain states targeted in Katz are categorized based on the level of alertness of the subject. (Col. 1, line 14 to 34). These states include sleep states associated with brain wave frequencies in the delta and theta ranges of 1.5 to 3.5 Hz and 3.5 to 7 Hz, respectively, a relaxed state associated with brain wave frequencies in the alpha range of 7.5 to 12.5 Hz, and an excited state associated with brain wave frequencies in the beta range of 12.5 to 20 Hz (*Id.*, *See also*, Col. 6, lines 16-35). Thus, each state of Katz is within a different EEG band, and Katz tries to move the subject from one state (in one band) to another state (in another band). At least the following distinctions can be made from the present claims.

Katz targets a desired brain <u>state</u>, which encompasses <u>a range</u> of frequenc<u>ies</u> in multiple EEG bands. Claim 12 of the present invention requires a device that is configured to move¹ an intrinsic frequenc<u>y</u>, not a state encompassing a range of frequenc<u>ies</u>. Further, movement of the intrinsic frequency of Claim 12 is within a <u>single</u> specified EEG band, and thus movement of the intrinsic frequency is within that single specified EEG band. In contrast, Katz' methods and devices move the subject's brain waves from one band to another, by teaching moving the subject from one brain state to a desired brain state. Brain states in Katz correlate to separate EEG bands in Katz (e.g. from relaxed in the alpha band to sleep in the delta or theta band).

Further, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject wherein the magnetic field

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¹ as a possible alternative to moving the Q-factor, coherence, or phase

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is configured to move a Q-factor of an intrinsic frequency of a brain of the subject within a specified EEG band as required in Claim 12.² As provided in the present application Figure 12, at least, and descriptions thereof, Q-factor is a measure of distribution around the intrinsic frequency within a single EEG band. Katz has no measurement or recognition of any such distribution around an intrinsic frequency, as it seeks to move brain states, without regard for any intrinsic frequency in a particular EEG band.

Likewise, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject wherein the magnetic field is configured to move a subject's coherence value required in Claim 12.³ Katz expresses a goal of achieving *symmetry in magnitude* of the EEG readings starting with asynchronous magnetic fields (0.5Hz, 5Hz) (see Col. 8, line 39-60, at least). Thus, any *secondary* preference toward coherent waves appears to also use *asynchronous magnetic fields*. (See, Column 8 line 39-60, at least). In contrast, the system of Claim 12 is configured to move⁴ a coherence value of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to a head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value.

Furthermore, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject wherein the magnetic field is configured to move an EEG phase between two sites in the brain of the subject of a specified EEG frequency.

Additionally, neither Katz nor Souder disclose or suggest comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject wherein the magnetic field is configured to increase the blood flow of at least one of the cortex and a lower region of the brain.

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² as a possible alternative to moving the intrinsic frequency, coherence, or phase

³ as a possible alternative to moving the intrinsic frequency, Q-factor, or phase

⁴ *Id*.

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In summary, both Souder and Katz fail to disclose or suggest all of the elements in the Claim 12 as amended, whether considered individually or in combination with each other or with any other reference. Withdrawal of this rejection and advancement of Claim 12 and all claims dependent thereon to allowance is respectfully requested.

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CONCLUSION

In light of the remarks set forth above, Applicants believe that the pending claims are under condition for allowance. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit account No. 23-2415 (Attorney Docket No. 35784-707.203). Respectfully submitted,

Date: June 9, 2014 /Kristin Havranek/ By:

Kristin Havranek Reg. No. 58,789

PATENT

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/944,591	11/11/2010	James William Phillips	35784-707.203	6039
WILSON, SONSINI, GOODRICH & ROSATI 650 PAGE MILL ROAD PALO ALTO, CA 94304-1050			EXAMINER	
			LANNU, JOSHUA DARYL DEANON	
			ART UNIT	PAPER NUMBER
			3735	
			NOTIFICATION DATE	DELIVERY MODE
			06/19/2014	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@wsgr.com

Case 5:23-cv-00626-XR DDAppneato29va Filed 04/1943 Plicant age 53 of 69 Advisory Action 12/944,591 PHILLIPS ET AL. Before the Filing of an Appeal Brief AIA (First Inventor to File) Status Examiner Art Unit JOSHUA D. LANNU 3735 --The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 09 June 2014 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. NO NOTICE OF APPEAL FILED 1. 🔀 The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Reguest for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods: \square The period for reply expires $\underline{3}$ months from the mailing date of the final rejection. The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection. The current period for reply expires months from the mailing date of the prior Advisory Action or SIX MONTHS from the mailing date of the final rejection, whichever is earlier. Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANT'S FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL 2. The Notice of Appeal was filed on ___. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). **AMENDMENTS** 3. X The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because a) They raise new issues that would require further consideration and/or search (see NOTE below); b) They raise the issue of new matter (see NOTE below); c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): 6. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the nonallowable claim(s). 7. For purposes of appeal, the proposed amendment(s): (a) 🛛 will not be entered, or (b) 🗌 will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended. AFFIDAVIT OR OTHER EVIDENCE 8. A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on 9. The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e). 10. The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1). 11. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER 12. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet. 13. Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). 3/20/2014 6/10/2014 14. Other:

Examiner, Art Unit 3735

/J. D. L./

STATUS OF CLAIMS

Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: 12-22.

15. The status of the claim(s) is (or will be) as follows:

Claim(s) withdrawn from consideration: 1-11.

/CHRISTINE HOPKINS/

Primary Examiner, Art Unit 3735

Continuation of 3. NOTE: The amendment changes the scope of the invention that would require further search and raises new 112 issues.

Continuation of 11. does NOT place the application in condition for allowance because: The amendment raises new 112 issues, specifically missing essential elements in regards to claims 12-22.

Claim 12 recites a magnetic field configured to perform several tasks. It is unclear how the magnetic field generator can create a magnetic field that performs these tasks without certain components like the EEG sensors (which would be required to identify what the current intrinsic frequency is in an EEG band) and the logic/circuitry that allows the magnetic field to be configured in such a manner to accomplish the listed tasks.

Applicant argues that Katz does not meet the limitations specified in the claim, specifically that Katz does not teach moving an intrinsic frequency of a brain of a subject within a specified EEG band, specifically moving the EEG band from one frequency in a single EEG band to another frequency of the same EEG band and also does not show that or moves a Q factor the intrinsic frequency. While this may be the case, the claim as written does not specify that limitation. The claim states that the magnetic field moves the an intrinsic frequency within a specified EEG band which would happen when you through different EEG bands to reach a specific one.

In addition, US 6,488,617 would also currently read on claims 12, 19, 20, and 21.

Examiner suggests amending the claim to include the missing elements and amending parts (a) and (b) of claim 12 to the following:

- --(a) move the intrinsic frequency toward a pre-selected intrinsic frequency within the specified EEG band using said magnetic field-- and
- --(b) c) move a Q-factor of the intrinsic frequency within a specified EEG band of the subject toward a pre-selected Q-factor of the intrinsic frequency using the magnetic field --

ELECTRONICALLY FILED ON JULY 7, 2014

Attorney Docket No. 35784-707.203 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: James William Phillips, et al.

Serial Number: 12/944,591

Filing Date: November 11, 2010

Title: SYSTEMS AND METHODS FOR

DEPRESSION TREATMENT USING NEURO-EEG SYNCHRONIZATION

THERAPY

Group Art Unit: 3735

Examiner: Lannu, Joshua

Confirmation No: 6039

Customer No. 21971

RESPONSE TO FINAL OFFICE ACTION AND REQUEST FOR CONTINUED EXAMINATION

MAIL STOP AF Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450

Commissioner:

This paper responds to the Final Office Action dated April 7, 2014 and the Advisory Action mailed June 19, 2014. Applicants submit herewith a Request for Continued Examination under 37 C.F.R. 1.114 with the appropriate fee.

Applicants respectfully request reconsideration of the above-referenced application in view of the following amendments and remarks.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 5 of this paper.

Conclusion begins on page 9 of this paper.

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AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings of claims in this application. Applicant reserves the right to pursue any subject matter of any canceled claims in this or any other appropriate patent application. Support for these claims is provided in the remarks following the listing of claims.

- 1. -11. (Cancelled)
- 12. (Currently Amended) A system for treating depression in a subject comprising: a magnetic field generator adapted to apply a magnetic field to a head of the subject, wherein the magnetic field generator comprises:
 - a) <u>information comprising</u>
 - i) a first intrinsic frequency of a brain of the subject within a specified EEG band,
 - ii) a Q-factor of the intrinsic frequency,
 - iii) a coherence value of a second intrinsic frequency and a third intrinsic frequency, wherein the second and third intrinsic frequencies are from two different sites in the brain of the subject within the specified EEG band, or
 - iv) an EEG phase between two sites in the brain of the subject of a specified EEG frequency, wherein the two sites are different; and
 - b) <u>a processor that controls the magnetic field, wherein the magnetic field is</u> <u>configured to</u>
 - moves move the intrinsic frequency of a brain of the subject in a preselected direction, up or down, within the a specified EEG band using said magnetic field,
 - ii) moves move a the Q-factor of the intrinsic frequency in a pre-selected direction, up or down, within the specified EEG band using the magnetic field,
 - iii) moves move a the coherence value of intrinsic frequencies among multiple sites in the brain of the subject within a specified EEG band by

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applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to a-the head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value, or

iv) moves move a the EEG phase between two sites in the brain of the subject of the specified EEG frequency, wherein the magnetic field comprises a first magnetic field that is in-phase with a second magnetic field or a first magnetic field that is out of phase with a second magnetic field; and

wherein the magnetic field increases the blood flow of <u>a</u> cortex of the brain or decreases the blood flow of a lower region of the brain.

- 13. (Previously Presented) The system of claim 12, comprising at least one permanent magnet.
- 14. (Previously Presented) The system of claim 12, wherein the magnetic field is generated by movement of at least one permanent magnet.
- 15. (Previously Presented) The system of claim 14, wherein the movement of the at least one said magnet is at a frequency between about 0.5 Hz and about 100 Hz.
- 16. (Previously Presented) The system of claim 14, wherein said movement comprises at least one of rotational motion, linear motion, and swing motion.
- 17. (Previously Presented) The system of claim 14, wherein said movement generates an alternating magnetic field.
- 18. (Currently Amended) The system of claim 12, further comprising logic that configured to controls the intrinsic frequency to be any intrinsic frequency between about 0.5 Hz and about 100 Hz in increments of about 0.1 Hz.
- 19. (Currently Amended) The system of claim 12, further comprising logic that configured to automatically changes the intrinsic frequency in response to EEG readings of a subject during treatment.
- 20. (Currently Amended) The system of claim 12, further comprising logic that configured to ealculates calculate the information from EEG data collected from the subject. within a

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specified EEG band, wherein said information comprises at least one of items listed below: (a) at least one intrinsic frequency; (b) Q factor of the at least one intrinsic frequency; (c) a coherence value of intrinsic frequencies; (d) an EEG phase; and (e) any combination thereof

- 21. (Previously Presented) The system of claim 12, further comprising: (a) a first electrode operable to detect electrical brain activity; and (b) a second electrode operable to detect a reference signal; wherein the first electrode is adapted to be located on the subject in at least one of: an area of low electrical resistivity on said subject, and an area with substantially no electrical impulse interference on said subject, and wherein the second electrode is adapted to be located on the subject.
- 22. (Previously Presented) The system of claim 12, further comprising a device configured to measure blood flow of at least one of the cortex and a lower region of the brain.

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REMARKS

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The following remarks are in response to the Examiner's Final Office Action dated April 7, 2014 and Advisory Action dated June 19, 2014. Claims 12, 18-20 are amended. Support for claim amendments can be found in Paragraphs [0342], [0450], [459] to [463], and [468], at least, and the application as filed. Claims 1-11 (previously withdrawn) are cancelled. Claims 12-22 are pending. Reconsideration is respectfully requested in light of the following remarks.

Claim Rejections - 35 USC § 112

Claims 12-22 were rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as allegedly being indefinite for failing to particularly point and distinctly claim the subject matter which the inventor or a joint inventor regards as the invention.

Claim 12 was rejected for reciting "a head" in line 9. Applicants thank the Examiner's for the suggestion to cite "the head". Applicants have amended the claim as suggested, therefore, the rejection is moot. Withdrawal of such rejection is respectfully requested.

Claims 12-22 as presented in the response to the Examiner's Final Office Action dated April 7, 2014 were noted in the Advisory Action dated June 19, 2014 as allegedly missing essential elements. Without conceding the appropriateness of the rejection, Applicants have amended Claim 12 in order to clarify how the magnetic field is configured to perform the claimed functions and expedite examination; therefore, the rejection is moot. Withdrawal of such rejection is respectfully requested.

Claim Rejections – 35 USC § 102

Claims 12-17 were rejected under 35 U.S.C. 102(b) as being anticipated by 6,001,055 ("Souder").

Without conceding the appropriateness of the rejection, Applicants appreciate the Examiner's suggestion to obviate the alleged intended use rejection; and applicants have

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amended the claims as suggested in order to expedite examination, therefore, the rejection is moot. Withdrawal of such rejection is respectfully requested.

Claims 12 and 18-22 were rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by US 6,488,617 ("Katz").

Applicants appreciate the Examiner's suggestion in the Final Office Action dated April 7, 2014 to obviate the alleged intended use by interpretation of certain claim language. Applicants also thank Examiner for the suggestion of amending parts (a) and (b) of claim 12 in the Advisory Action dated June 19, 2014. Without conceding the appropriateness of the rejection, Applicants have amended the claims to address Examiner's points, therefore, Applicants believe the rejection of Claim 12 and 18-22 is obviated by such amendments.

The device of Katz describes <u>a feedback system</u>, which <u>in real time</u>, tries to move a subject <u>from a current brain state into a desired brain state</u> via magnetic stimulation. Brain states targeted in Katz are categorized based on the level of alertness of the subject. (Col. 1, line 14 to 34). These states include sleep states associated with brain wave frequencies in the delta and theta ranges of 1.5 to 3.5 Hz and 3.5 to 7 Hz, respectively, a relaxed state associated with brain wave frequencies in the alpha range of 7.5 to 12.5 Hz, and an excited state associated with brain wave frequencies in the beta range of 12.5 to 20 Hz (*Id.*, *See also*, Col. 6, lines 16-35). Thus, each state of Katz is within a different EEG band, and Katz tries to move the subject from one state (in one band) to another state (in another band). At least the following distinctions can be made from the present claims.

Katz targets a desired brain <u>state</u>, which encompasses <u>a range</u> of frequenc<u>ies</u> in multiple EEG bands. Claim 12 of the present invention requires a device that is configured to move¹ an intrinsic frequenc<u>y</u>, not a state encompassing a range of frequenc<u>ies</u>. Further, movement of the intrinsic frequency of Claim 12 is within a <u>single</u> specified EEG band in a preselected direction, up or down, and thus movement of the intrinsic frequency is only within that single specified EEG band and only in a pre-selected direction, up or down (support in Paragraph

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¹ as a possible alternative to moving the Q-factor, coherence, or phase

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[459]). In contrast, Katz' methods and devices move the subject's brain waves from one band to another, by teaching moving the subject from one brain state to a desired brain state. Brain states in Katz correlate to separate EEG bands in Katz (e.g. from relaxed in the alpha band to sleep in the delta or theta band).

Further, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject, wherein the magnetic field generator comprises information comprising a Q factor of an intrinsic frequency of a brain of the subject and a processor that controls the magnetic field and wherein the magnetic field is configured to move the Q-factor in a pre-selected direction, up or down, within a specified EEG band using said magnetic field as required in Claim 12.² As provided in the present application Figure 12, at least, and descriptions thereof, Q-factor is a measure of distribution around the intrinsic frequency within a single EEG band. Katz has no measurement or recognition of any such distribution around an intrinsic frequency, as it seeks to move brain states, without regard for any intrinsic frequency in a particular EEG band.

Likewise, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject, wherein the magnetic field generator comprises information comprising a coherence value of two intrinsic frequencies, wherein the two intrinsic frequencies are from two different sites in the brain of the subject within the specified EEG band and a processor that controls the magnetic field, and wherein the magnetic field is configured to move the coherence value required in Claim 12. Katz expresses a goal of achieving *symmetry in magnitude* of the EEG readings starting with asynchronous magnetic fields (0.5Hz, 5Hz) (see Col. 8, line 39-60, at least). Thus, any *secondary* preference toward coherent waves appears to also use *asynchronous magnetic fields*. (See, Column 8 line 39-60, at least). In contrast, the system of Claim 12 is configured to move⁴ the coherence value by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to a head of the subject

⁴ *Id*.

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² as a possible alternative to moving the intrinsic frequency, coherence, or phase

³ as a possible alternative to moving the intrinsic frequency, Q-factor, or phase

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and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value.

Furthermore, Katz fails to disclose or suggest a system comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject, wherein the magnetic field generator comprises information comprising an EEG phase between two different sites in the brain of the subject of a specified EEG frequency and a processor that controls the magnetic field and wherein the magnetic field is configured to move the EEG phase.

Additionally, neither Katz nor Souder disclose or suggest comprising a magnetic field generator adapted to apply a magnetic field to a head of a subject, wherein the magnetic field generator comprises information and a processor that controls the magnetic field and wherein the magnetic field is configured to increase the blood flow of at least a cortex of the brain or decrease the blood flow of a lower region of the brain.

In summary, both Souder and Katz fail to disclose or suggest all of the elements in the Claim 12 as amended, whether considered individually or in combination with each other or with any other reference. Withdrawal of this rejection and advancement of Claim 12 and all claims dependent thereon to allowance is respectfully requested.

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CONCLUSION

In light of the remarks set forth above, Applicants believe that the pending claims are under condition for allowance. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit account No. 23-2415 (Attorney Docket No. 35784-707.203).

Respectfully submitted,

Date: July 7, 2014 By: /Kristin Havranek/

Kristin Havranek Reg. No. 58,789 **PATENT**

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EXAMINER'S AMENDMENT

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/7/2014 has been entered.

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kristin Havranek on 7/16/2014.

The application has been amended as follows:

- 12. (Currently Amended) A system for treating depression in a subject comprising: a magnetic field generator adapted to apply a magnetic field to a head of the subject, wherein the magnetic field generator comprises:
- a) <u>a non-transitory computer readable medium containing a subject data value</u> information comprising

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- i) a first intrinsic frequency of a brain of the subject within a specified EEG band,
- ii) a Q-factor of the first intrinsic frequency,
- iii) a coherence value of a second intrinsic frequency and a third intrinsic frequency, wherein the second and third intrinsic frequencies are from two different sites in the brain of the subject within the specified EEG band, or iv) an EEG phase between two sites in the brain of the subject of a specified EEG frequency, wherein the two sites are different; and
- b) a processor that controls configured to control the magnetic field based on said subject data value, wherein the magnetic field is configured to
- i) move the <u>first</u> intrinsic frequency in a pre-selected direction, up or down, within the specified EEG band using said magnetic field,
- ii) move a the Q-factor of the first intrinsic frequency in a pre-selected direction, up or down, within the specified EEG band using the magnetic field,
- iii) move a the coherence value by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to the head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value, or
- iv) move the EEG phase of the specified EEG frequency, wherein the magnetic field comprises a first magnetic field that is in-phase with a the second magnetic field or a first magnetic field that is out of phase with a the second magnetic field; and

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wherein the magnetic field increases the blood flow of a cortex of the brain or decreases the blood flow of a lower region of the brain.

20. (Currently Amended) The system of claim 12, further comprising logic configured to calculate the subject data value information from EEG data collected from the subject.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 7/8/ is being considered by the examiner.

Allowable Subject Matter

- 4. Claims 12-22 are allowed.
- 5. The following is an examiner's statement of reasons for allowance:
- 6. In regards to claim 12, the prior art does not teach or suggest a device, as claimed by Applicant, that includes the following components:
 - a) a non-transitory computer readable medium containing a subject data value comprising
 - i) a first intrinsic frequency of a brain of the subject within a specified EEG band,
 - ii) a Q-factor of the first intrinsic frequency,

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- iii) a coherence value of a second intrinsic frequency and a third intrinsic frequency, wherein the second and third intrinsic frequencies are from two different sites in the brain of the subject within the specified EEG band, or
- iv) an EEG phase between two sites in the brain of the subject of a specified EEG frequency, wherein the two sites are different; and
- b) a processor configured to control the magnetic field based on said subject data value, wherein the magnetic field is configured to
 - i) move the first intrinsic frequency in a pre-selected direction, up or down, within the specified EEG band using said magnetic field,
 - ii) move a the Q-factor of the first intrinsic frequency in a pre-selected direction, up or down, within the specified EEG band using the magnetic field,
 - iii) move a the coherence value by applying the magnetic field and a second magnetic field that is asynchronous with the magnetic field close to the head of the subject and reducing the coherence value, or by applying the magnetic field and the second magnetic field that is synchronized with the magnetic field close to the head of the subject and raising the coherence value, or
- iv) move he EEG phase of the specified EEG frequency, wherein the magnetic field comprises a first magnetic field that is in-phase with the second magnetic field or a first magnetic field that is out of phase with the second magnetic field; and wherein the magnetic field increases the blood flow of a cortex of the brain or decreases the blood flow of a lower region of the brain.

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7. Claims 13-22 are dependent on allowable matter from claim 12 and are thus allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSHUA D. LANNU whose telephone number is (571)270-1986. The examiner can normally be reached on Monday-Friday 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles A. Marmor can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. D. L./ Examiner, Art Unit 3735

/CHRISTINE HOPKINS/ Primary Examiner, Art Unit 3735